PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of

Wridzer Jan Willem BAKKER et al. Attn: PCT Branch

Application No. New U.S. National Stage of PCT/EP2004/004506

Filed: October 13, 2005 Docket No.: 125619

For: ANTISOLVENT SOLIDIFICATION PROCESS

SUBMISSION OF THE ANNEXES TO THE INTERNATIONAL PRELIMINARY EXAMINATION REPORT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Attached hereto are the annexes to the International Preliminary Examination Report (Form PCT/IPEA/409). The attached material replaces the claims.

Respectfully submitted,

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Amended set of claims

1. Antisolvent solidification process for preparing a solid composition comprising at least one organic or inorganic compound, wherein a liquid medium comprising at least one dissolved organic or inorganic compound is forced through a membrane which is positioned in a membrane module into one or more antisolvents or wherein one or more antisolvents are forced through a membrane which is positioned in a membrane module into a liquid medium comprising at least one organic or inorganic compound, and whereby the process is carried out as a continuous process, yielding a composition comprising solid particles comprising said organic and/or inorganic compound(s).

2. A process according to claim 1 wherein the solidification is a crystallisation, the prepared solid particles are crystalline particles, the organic or inorganic compound is a crystallisable compound, and, optionally, said crystalline particles are recovered from the process.

3. A process according to any one of claims 1-2 wherein the liquid medium is separated from the one or more antisolvents by means of nanofiltration and wherein, optionally, the liquid medium and/or the antisolvent(s) is/are recycled.

4. A process according to any one of claims 1-3 wherein an emulsion is formed before said composition comprising solid particles is obtained.

5. A process according to any one of claims 1-4 wherein a nonsolvent is present in the liquid medium and/or in the one or more antisolvents.

6. A process according to any one of claims 1-5 wherein the organic or inorganic compound is selected from the group consisting of transition metal compounds, transition metal salts, alkali salts, alkali earth salts, fatty acids, proteins, saccharides, aminoacids, and pigments.

7. A process according to any one of claims 1-6 wherein the solid particles essentially consist of particles of only one inorganic or organic compound.

8. A process according to any one of claims 1-7 wherein the inorganic or organic compound is a pharmaceutical compound.

9. A process according to claim 8 wherein the pharmaceutical compound is selected from the group consisting of tibolone, progesterone, desogestrel, and 3-keto-desogestrel (etonogestrel).

10. A process according to any one of claims 1-7 wherein the solid composition comprises a mixture of two or more pharmaceutical compounds.

11. A process according to any one of claims 1-3 wherein a composition comprising solid particles is prepared, in which composition at least part of the particles consists of a core coated with one or more solid coatings of one or more organic or inorganic coating materials, by forcing a liquid medium comprising dissolved organic or inorganic coating material through a membrane into a suspension of particles to be coated in one or more antisolvent(s) for said coating material.

12. A process according to claim 11 wherein the prepared solid composition comprises particles having a core comprising a pharmaceutical compound coated with at least one or more coating materials which comprise a pharmaceutical compound.

13. Crystalline particles obtainable by the process of any one of claims 1-12 comprising at least one pharmaceutical compound which is preferably selected from the group consisting of tibolone, progesterone, desogestrel, and 3-keto-desogestrel (etonogestrel) showing only little and preferably essentially no agglomeration and having a span of the particle size distribution immediately after the crystallisation step of below 3.

14. A pharmaceutical dosage form comprising crystalline particles according to 13.

15. A pharmaceutical dosage form according to claim 14 wherein the dosage form is a tablet.

16. Use of the process according to any one of claims 1-12 or the crystalline particles according to claim 13 in the preparation of a pharmaceutical dosage form.